REMARKS

Claim Status

Claims 36, 38, 41-43, 46 and 48 are pending in the present application. No additional claims fee is believed to be due.

Claims 1-35, 37, 39, 40, 44, 45, and 47 have been previously canceled without prejudice.

Rejection Under 35 USC §103(a)

Claim 36, 38, 41-43, 46 and 48 are rejected under 35 USC §103(a) as being unpatentable over US Patent No. 5,112,604 to Beaurline ("Beaurline") in view of US Patent No. 4,680,312 to Johnson ("Johnson") and Remington's Pharmaceutical Sciences, 18th edition (page 340) ("Remington").

The Examiner asserts that Beaurline discloses aqueous suspension formulations having a drug, a wetting agent, a hydrocolloid gum, colloidal silicon dioxide, antifoaming agent, citric acid, water and other components. The Examiner acknowledges that Beaurline does not disclose particle size of the silicon dioxide, but asserts that Beaurline discloses 'colloidal' silicon dioxide which is defined in the present Specification. The Examiner also acknowledges that Beaurline does not disclose the amount of water in the composition, but asserts that the Examples of Beaurline discloses simple syrup preparations which would contain water. Therefore, the Examiner asserts that it would have been obvious to include the appropriate amount of water to the composition of Beauline to prepare an oral liquid composition. The Examiner also asserts that although Beaurline only teaches 0.2 to 2% silicon dioxide, and the present Claims recited 3% to 50%, the instant claims recite a wide range that includes very low and very high amounts. However, the Examiner does not specify why such a range would have been obvious.

The Examiner also asserts that Johnson discloses stable gels of prostaglandin having silicon dioxide as a gel forming agent. The Examiner asserts that Johnson discloses that the use of colloidal silicon dioxide as a gelling agent is known in the art.

The Examiner asserts that Johnson discloses colloidal silicon dioxide at amounts from 3% to 15%, and that a lower percentage of silicon dioxide results in lower viscosity.

Furthermore, the Examiner asserts that Remington discloses that colloidal silicon dioxide is used to prepare gells and is used as a thickener.

Thus, the Examiner asserts that use of colloidal silicon dioxide to form gels is widely recognized, and that lower amounts of silicon dioxide render low viscosity gels, and that a minimum amount (of colloidal silicon dioxide) is necessary to achieve the minimum desired viscosity for the selected liquid.

Therefore, the Examiner asserts that it would have been obvious that the silicon dioxide of Beaurline still possess the ability to form a gel, in the amounts disclosed therein, even though having such a low amount (0.2% to 2%) of silicon dioxide.

Finally, the Examiner references a '620 document, but does not cite such a document on the form PTO892. Thus, the Applicant can not address said document.

The Applicants respectfully traverse the rejection and submit that the Examiner has not established a *prima facie* case of obviousness. See MPEP § 2143.01. Even in light of *KSR v. Teleflex* 127 S.Ct. 1727 (2007) ("*KSR*"), in order for an obviousness rejection to stand, there should at least be some need or predictability in the achieved result, considering the common sense of one of ordinary skill in the art.

With respect to Beaurline, discloses only a stable, uniform sustained-release suspension of thephylline, wherein the theophylline is suspended in polymeric particles. Beaurline does not provide need, motivation or expectation of success for the use of other pharmaceutical actives. Furthermore, with particular respect to the amount of silicon dioxide, Beaurline discloses a maximum of 2% silicon dioxide. Beaurline desires to create an aqueous pharmaceutical suspension that maintains the medicament in suspension for a prolonged period of time without shaking. Beaurline does not disclose a gel. Thus, Beaurline does not provide need or motivation for adding greater amounts of silicon dioxide, or for creating a gel. Furthermore, Beaurline does not disclose, suggest or provide motivation or expectation of success for creating a composition or method of administering a *liquid aqueous mucoretentive composition* that forms a gel-like mixture

upon contact with a mucosal surface as recited in the Claims. As defined in the Specification at page 7, beginning at line 10, the term "gel" describes the substance resulting from the combination of mucin/saliva mixture and the formulation of the present invention. Beaurline does not disclose, suggest or provide motivation or expectation of success for a composition that would form a gel-like mixture upon contact with a mucosal surface as recited in the present Claims. The objective of Beaurline is to create a stable suspension, not to create a gel-like mixture upon contact with a mucosal surface and thus Beaurline provides no motivation for, or expectation of success in, creating a *liquid aqueous mucoretentive composition* that forms a gel-like mixture upon contact with a mucosal surface.

In contrast to Beaurline, the composition of Johnson is a gel when made and remains a gel. Johnson provides an improved class of stable gels of prostaglandin E. While the composition is gelled by the addition of colloidal silicon dioxide, the resultant composition is a free-flowing gel. See Column 2, lines 60-68. In addition, Johnson adds that the compositions in the form of gels are more readily handled and formulated than liquids. See Column 3, lines 20-38. In particular, Johnson premixes the components to create gelling. See Column 4, lines 3-7. Gelling does not occur upon contact with a mucosal surface. Johnson therefore, does not disclose or suggest, or provide need, motivation or expectation of success for creating a *liquid aqueous mucoretentive composition* that forms a gel-like mixture upon contact with a mucosal surface as recited in the Claims.

Remington is cited for disclosure that amorphous silica can be used as a gas adsorbent, desiccant, carrier, filler, thickener and abrasive. However, Remington does not disclose or suggest use of, or appropriate amounts for use of silica, in a *liquid aqueous mucoretentive composition* that forms a gel-like mixture upon contact with a mucosal surface.

With respect to the Examiner's assertions that the Applicants have not shown that lower amounts of silicon dioxide do not form gels, an Applicant, even under the analysis of *KSR* is not required to show explicit teaching away show non-obviousness. However, the Examiner attempts to require a showing of explicit teaching away. The Examiner asserts that it would have been obvious from Beaurline that the silicon dioxide of Beaurline still possesses the ability to form a gel at the amounts disclosed by Beaurline and the Applicants have not shown otherwise. An Applicant is not required to show explicit teaching away. However, as discussed above, Beaurline specifically states that the compositions disclosed therein are aqueous suspensions. Beaurline does not state or disclose that the compositions therein are or can form gels. Thus, Beaurline itself teaches that the compositions therein are not gels.

Finally, the Applicants assert that unexpected advantages have been disclosed in the present Specification. For example, see page 2, lines 10-21 wherein the benefits of a flowable liquid that becomes a viscous gel are discussed. See also page 6, lines 28-33 wherein the conversion to a viscous gel-like mixture is discussed. None of the cited documents disclose, suggest or provide motivation or expectation of success for creating such a composition, or method.

Assuming *arguendo* Beaurline, Johnson and Remington were combined, one would still have fallen short of the Applicants' claimed invention, perhaps to have arrived at a gel formulation for theophylline or a liquid formulation for prostaglandin E. But, one would not have arrived at the presently claimed invention.

Therefore, the Applicants respectfully submit that none of the cited documents, whether taken alone or in combination, discloses, suggests or provides motivation or expectation of success for the invention as presently claimed.

Conclusion

This response represents an earnest effort to place the present application in proper form and to distinguish the invention as claimed from the applied document(s). In view of the foregoing, reconsideration of this application, and allowance of all pending claim(s) are respectfully requested.

Respectfully submitted,

THE PROCTER & GAMBLE COMPANY

By /Kristin Kohler/
Kristin Kohler
Registration No. 41,907
(513) 622-3371

Date: June 5, 2008
Customer No. 27752